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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,780	11/30/2001	Roman Sakowicz	CYTOP083	9903

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT PAPER NUMBER

1645

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/006,780

Applicant(s)

SAKOWICZ ET AL.

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 12 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-15, 17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) 17 and 18 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-15 is/are allowed.
- 6) ☒ Claim(s) 8-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/29/03, 2/2/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Applicant's response to first action on merits filed on 3/12/04 is acknowledged.

Status of Claims

2. Claims 8-15 and 17-18 are currently pending in the application.

Claims 11-15 have been amended.

Claims 8-15 are under prosecution.

Claims 17-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Specification – Informalities withdrawn

3. In view of amendment to the specification, the specification informalities have been withdrawn.

Information Disclosure Statement

4. The Information Disclosure Statement filed on 2/2/04 is acknowledged and a signed copy of the same is enclosed to this office action. Applicant requested the examiner to send a signed copy of page 1 of IDS filed on 9/29/03, as the applicant did not receive in the previous office action. A signed copy 9/29/03 of the same and a signed copy of the IDS filed on 2/2/04 are enclosed to this office action.

Written Description Rejection - 35 USC 112 withdrawn

5. Upon further review of the application and the arguments of record, the rejection under 35 U.S.C. 112, first paragraph written description is withdrawn.

Claim Rejections - 35 USC § 102 withdrawn

In view of amendment to claims 11-15, the rejection claims under 35 U.S.C. 102(b) as being anticipated by Ristic et al U.S. Patent 4,767,622 is withdrawn.

Scope of enablement Rejection - 35 U.S. C. 112, first paragraph, maintained

6. The rejection of claims 8-10 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide comprising the amino acid sequence SEQ ID NO: 2, 4, 6, 8 and 10 having microtubule stimulated ATPase activity and/or depolymerizes microtubules, does not reasonably provide enablement for an isolated protein comprising a sequence that has greater than 90% amino acid sequence identity to SEQ.ID.NO: 2, 4, 6, 8 or 10 as measured using a sequence comparison algorithm. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly, connected, to make and use the invention commensurate in scope with these claims is maintained as set forth in the previous office action.

The specification teaches the recombinant kinesin motor protein, SEQ.ID.NO: 2 from merozoites of *Plasmodium falciparum*. The specification discloses the claimed protein could be used as target protein for measuring ATPase activity and microtubule depolymerizing activity etc (pages 46-48). However an isolated protein comprising a sequence that has greater than 90% amino acid sequence identity to SEQ.ID.NO: 2, 4, 6, 8 or 10 having microtubule stimulated ATPase activity and/or depolymerizes microtubules are not disclosed. Moreover, protein chemistry is probably one of the most unpredictable areas of biotechnology and the art teaches that the significance of any particular amino acid sequences (i.e. fragments) for different aspects of biological activity cannot be predicted a priori and must be determined empirically on a case-by-case basis (Rudinger et al, in "PEPTIDE HORMONES", edited by Parsons, J.A., University Park Press, June 1976, page 6). The art specifically teaches that even a single amino acid change in a protein leads to unpredictable changes in the biological activity of the protein. For example, replacement of a single lysine residue at position 118 of the acidic fibroblast growth factor by glutamic acid led to a substantial loss of heparin binding, receptor binding, and biological-activity of the protein (Burgess et al., *The Journal of Cell Biology*, 111:2129-2138, 1990). In transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine, or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biologic activity of the mitogen (Lazar et al., *Molecular and Cellular Biology*, 8(3): 1247-1252, 1988). These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification, will often dramatically affect the biological activity of a protein. Proteins with replacement of single amino acid residues may lead to both structural and functional changes in biological activity and immunological recognition. For example, Jobling et al. (*Mol. Microbiol.* 1991, 5(7): 1755-67 teaches a panel of single amino acid substitutions by oligonucleotide directed mutagenesis which products proteins that differ in native conformation, immunological recognition, binding and toxicity, thus exemplifying the importance of structural components to both biological function and immunological recognition. Applicants have not taught an isolated protein SEQ.ID.NO: 4, 6, 8, or 10 having microtubule stimulated ATPase activity and depolymerizes

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microtubules and an isolated protein comprising a sequence that has greater than 90% amino acid sequence identity to SEQ.ID.NO: 2, 4, 6, 8 or 10 that is functional as an immunogenic composition or is capable of use as a diagnostic using immunological means of recognition.

Isolated protein SEQ.ID.NO: 4, 6, 8, or 10 having microtubule stimulated ATPase activity and depolymerizes microtubules and an isolated protein comprising a sequence that has greater than 90% amino acid sequence identity to SEQ.ID.NO: 2, 4, 6, 8 or 10, it is not enabled for this language because it fails to enable the skilled artisan to envision the detailed structure and function of the claimed proteins. In view of the unpredictability of the art, the lack of teachings of the specification, it would require undue experimentation on the part of the skilled artisan to practice the invention as claimed.

Applicant's arguments filed on 3/11/04 are fully considered but found to be non persuasive.

Applicant states that the rejection made by the examiner is not correct and cites the Federal Circuit case law and explains to the examiner what constitutes experimentation.

Applicant states that the experimentation is not deemed to be undue if (1) the experimentation is routine, OR (2) the specification provides reasonable guidance in the direction the experimentation should proceed and the present specification satisfies both.

The examiner disagrees with the applicant because the examiner followed the standard In re Wands analysis in the rejection made in the previous office action as stated above. The specification neither provides guidance nor it is routine in the art of Plasmodium recombinant technology to obtain the claimed variant.

With respect to first issue, i.e., the experimentation is routine, applicant cites textbook Creighton and states that the edition of the text book predates the priority date of the instant application and therefore, one could readily prepare the variants. The examiner disagrees with the applicant because even though the textbook in general teaches about introducing deletions and insertions but did not teach after introducing said deletion and insertion that the nucleic acid still encodes the functional protein. The examiner stated the unpredictability associated with it in the previous office action as one amino acid change would alter the function of the protein.

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With respect to the second issue, applicant states that the specification teaches and provides guidance to relatively few amino acids should be modified to minimize the alteration of the protein activity and paragraphs 0065 and 0068 teach homologous protein HsKin-I -3.

The examiner has reviewed the application and noted that the claimed motor protein shares approximately 50% identity with HsKin-I -3. However, the specification does not provide the guidance to obtain the claimed variant from Plasmodium parasite because parasites are known to change their antigenicity during the life cycle. The specification provides how the claimed protein can be compared to other proteins using sequence comparison computer algorithms only. In view of the unpredictability associated with making and using the nucleic acids encoding the variant encompassed in the scope of the claims as set forth above, the lack of teaching of variant, lack of working examples commensurate in scope with the instant claims, the skilled artisan would be forced into undue experimentation to practice (i.e. make and use) the invention as is broadly claimed.

Remarks

7. Claim 11 -15 are allowed.

Claims 8-10 are rejected.

Conclusion

8. This application contains claims 17-18 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

9. THIS ACTION IS MADE FINAL. See MPEP ' 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the

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mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

10. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is (571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

5/26/04


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